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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/809,545	03/14/2001	Lawrence W. Stanton	SCIOS.017A	5472

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EXAMINER

MARTINELL, JAMES

ART UNIT PAPER NUMBER

1631

DATE MAILED: 03/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/809,545

Applicant(s)

STANTON ET AL.

Examiner

James Martinell

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2002 and 11 February 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 2, 8-19 and 23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-7, 20-22 and 24-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6 & 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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Applicant's election of Group I, claims 1-7 and 20-26 in Paper No. 9 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Newly submitted claim 23 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 23 has been amended (paper no. 11, filed February 11, 2003) so that it now includes only antibody kits and now properly belongs only in Group III as outlined in the requirement for restriction mailed October 2, 2002.

Although claim 2 was originally placed in Group I, it is drawn to a non-elected SEQ ID NO. Accordingly, claim 2 is independent and distinct from the elected invention and is withdrawn from consideration.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 23 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 2, 8-19 and 23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 9.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-7, 20-22, and 24-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are vague, indefinite, and incomplete.

- (a) The recitation of more than the elected invention (claim 1) renders the claims vague and indefinite. Mention of non-elected SEQ ID NOs should be deleted.

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- (b) The recitation of "having at least one biological activity of the polypeptide encoded by clone P00184_D11 (SEQ ID NO: 1)" (claim 1(d) and (e)) is vague, indefinite, and incomplete because no biological activity for the polypeptide that is SEQ ID NO: 2 is disclosed.
- (c) The recitation of "at least about 50" (claim 1(e) is vague and indefinite because 48 is about 50 and 49 is at least 48, but 49 is not at least 50. Thus, the metes and bounds of the claims are not clear.
- (d) The recitation of "(e.g. human)" (claim 20) is vague and indefinite. It is not clear whether the claim embraces human homologues.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polynucleotides that encode SEQ ID NO: 2, does not reasonably provide enablement for "an antisense oligonucleotide capable of hybridizing with, and inhibiting the translation of, the mRNA encoded by a gene encoding a polypeptide of SEQ ID NOs: 2" (claim 1(i)). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The downregulation of translation by antisense methods is unpredictable (*e.g.*, see Branch, Trends in Biological Sciences 23: 45 (February 1998), especially: Abstract; page 45, column 1, first sentence; page 46, column 3, first sentence of first full paragraph; page 47, paragraph bridging columns 1-2; paragraph bridging pages 47-48; page 49, paragraph bridging columns 1-2; page 49, last full paragraph; and page 49). The instant application does not teach one of skill in the art how to achieve downregulation of SEQ ID NO: 2 by antisense methods in view of the difficulties outlined in Branch.

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 5, and 6 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Bonaldo et al (Genome Res. 6: 791 (1996)). Bonaldo et al discloses a DNA that shares 178 contiguous nucleotides with SEQ ID NO: 1 (see the alignment attached to the copy of the reference and enclosed with this Office action). Thus, the DNA of Bonaldo et al will hybridize under stringent conditions to SEQ ID NO: 1 (claim 1(d)). Kennell et al (Progr. Nucl. Acid Res. Mol. Biol. 11: 259 (1971)) is cited here to show that a DNA duplex of 25-50 nucleotides is maximally stable (*e.g.*, see the paragraph bridging pages 260-261) and will thus remain a duplex under stringent hybridization conditions. Since the DNA in Bonaldo et al was sequenced, it was necessarily contained within a vector and host cell (claims 5 and 6).

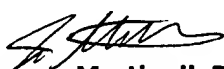
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Claims 4 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonaldo et al (Genome Res. 6: 791 (1996)) in view of applicants' admitted state of the prior art (*e.g.*, instant application, pages 29-36). The discussion of Bonaldo et al hereinabove is incorporated here. Applicants acknowledge the use of expression vectors to produce proteins in recombinant host cells to be old. It would have been obvious for one of ordinary skill in the art at the time the invention was made to express the DNA of Bonaldo et al in the admittedly old manner in order to produce large amounts of the polypeptide encoded by the DNA of Bonaldo et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Martinell whose telephone number is (703) 308-0296. The fax phone number for Examiner Martinell's desktop workstation is (703) 746-5162. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be e-mailed to james.martinell@uspto.gov. Since e-mail communications may not be secure, it is suggested that information in such requests be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 305-4028. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



James Martinell, Ph.D.
Primary Examiner
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